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EXAMINER
SCHMICKEL, D

18M2/0810

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ART UNIT	PAPER NUMBER
1814	17

DATE MAILED:
08/10/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 5-10-93 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire three month(s), ~~three~~ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-7, 27 & 28 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-7, 27 & 28 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

Claims 1-7 and 27-28 are pending.

1. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

2. Claims 1-7 and 27-28 are again rejected under 35 U.S.C. § 103 as being unpatentable over Laboureur et al. in view of Reedy et al. and Riggs or Neilsen et al. in further view of Janson or Mannson-Rahemtulla et al., Nakagawa et al. or Burton et al.

Applicants have traversed this rejection by arguing that (i)Examiner has failed to appreciate the relationship between pseudo-affinity chromatography and recombinant expression, and (ii) failed to place appropriate weight on the Larbre Declaration.

Applicants point out that the declaration of Larbre indicates after numerous failures in further purification using traditional purification techniques only pseudo-affinity

chromatography specially modified for urate oxidase led to a preparation of greater than 16 U/mg. That the urate oxidase could not be purified to a sufficient extent to sequence prior to pseudo-affinity chromatography and, therefore, it could not be sequenced. That it is unobvious as evidenced by the interest and that no one has done it in the seventeen years since the Laboureur patent. Finally, the Reedy et al. method of protein purification will not work with A. flavus.

Applicants argue that the rejection is devoid of support for his doubting of the Labourer Declaration as he has not point to teachings in the prior art suggesting the method employed by Applicants and modifications thereto were within the purview of one of ordinary skill in the art and the existance of a reasonable expectation of success. Applicants state that examiner has stated it would be obvious to try which is not an appropriate standard for obviousness.

Applicants' arguments have been considered but are not deemed persuasive. As a general statement Examiner finds Applicants believe an inappropriate weight should be placed on the importance of the Larbre Declaration. The Declaration is unworthy of the weight desired as it is devoid of data and light on specific facts. Examiner suggests Applicants see MPEP 716 to see how Examiner will evaluate the submitted Declaration. Specifically, the first paragraph refers to sufficient facts (emphasis added by Examiner) to overcome the rejection.

Applicants' discussion that Laboureur's urate oxidase (UO) is not pure enough to get sequences is not convincing. It is pointed out that Laboureur got pure enough UO to get amino acid composition and that even a band of UO on a gel is a sufficient protein to get a amino acid sequence. Applicants' argument that 'as no one has done this in seventeen years it is not obvious' is not understood. Do Applicants mean that 35 U.S.C. § 103 rejections are improper? If someone else had anticipated the invention and reported it in the prior art, Examiner would probably have rejected the claimed invention under 35 U.S.C. § 102. The statute 35 U.S.C. § 103 refers to the rejection where the invention is not anticipated, but one of ordinary skill in the art has the invention and would have been motivated to combine parts of the prior art to make the invention as is the case here. It is not clear why the method of Reedy et al. would not work with A. flavus, but Applicants are reminded that the reference include reasonable inferences and routine experimentation if Applicants are referring to trivial deficiencies.

Applicants view of Examiners role in making a proper rejection is incorrect. Applicants claim that Examiner must reject the claims by determining that the method Applicant used to produce the product is obvious is incorrect. Applicants are incorrect as Applicants are not claiming a method of purification. It is noted Examiner has not stated the exact

method Applicants have used to purify UO is obvious. Applicants are claiming a UO of a specific purity. Examiner has repeatedly stated the high purity UO is obvious. As the UO is being claimed it is assumed that the UO is the same regardless if it is purified by pseudo affinity chromatography or by any other purification method. Activity alone does not prove the proteins are different, unless perhaps both are crystallized then dissolved and assayed. Finally, Examiner can not locate the sentence where he has said it is obvious to try. Examiner is appreciative that Applicants have reminded him that this is an inappropriate standard for obviousness and if Examiner thinks of stating such in an Office Action Applicants can be assured he will remember that a reasonable expectation of success is also needed.

3. No Claims are allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Schmickel whose telephone number is (703) 308-4202.

David Schmickel, Ph.D.
August 9, 1993

ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
GROUP 180